

REMARKS

Claims 3-4, 6, 8-9, 13-14, 16, 18-19, 21-22, and 24-38 were pending in the present application. Claims 3-4, 6, 8-9, 13-14, 16, 18-19, 21-22, were withdrawn from consideration. By virtue of this response, claims 24-38 are under consideration. Claims 24 and 31 are now amended. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicant believes the amendments do not present any new matter to the subject application. Claim 24 is amended to recite that the septal defect occluder comprises a shape memory frame that when not constrained self-expands to form a first and a second umbrella. Claim 31 is amended to recite a septal defect occluder comprising a shape memory frame with a proximal end, a mid point and a distal end wherein the frame can be constrained to fit within catheter; and when released from the catheter expands to form a first and a second umbrella.

Support for the amendments to claims 24 and 31 can be found in paragraph [0060], and [0079].

Rejections under 35 U.S.C. §102(e)

Claims 24-29 and 31-36 are rejected under 35 U.S.C. §102(e) as being anticipated by Huebsch et al. (5,853,422). Applicant disagrees.

The Office Action states that Huebsch teaches a tubular frame made of NITINOL where the frames form umbrellas that bend towards the midpoint of the frame.

However, when taken in its entirety Huebsch clearly fails to teach a self-expandable septal defect occluder. For example, in lines 16-20 of Col. 2, Huebsch states the need for a plug that is adjusted by mechanical means from a delivery configuration to a configuration which functions as a plug at the site of a defect. In addition, in cols. 5 and 6, Huebsch teaches a complex mechanism to lock the ends of the Huebsch device together. The Huebsch device also teaches mechanisms to lock the expanded device together, see Figs. 6-10.

Applicant notes that it is well established that “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220

USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (as also cited in MPEP §2141.02).

In this case, Huebsch clearly teaches a complex device that requires actuation for deployment. In contrast, the subject application teaches “a simple collapsible, compact closure device that can be delivered through a small catheter.” (See paragraph [0007] of the subject application). In addition, the subject application teaches that “[m]ost trans-catheter systems are mechanically complex and require a great deal of remote manipulation for deployment or retrieval. This extensive remote manipulation, such as by applying tension to one or more cables in order to deploy or to anchor the device in place, not only increases the difficulty of the procedure, but tends to increase the likelihood that the device will be improperly deployed. This can necessitate either retrieval or repositioning so as to effectively occlude the defect and minimize the risk of embolization.” (See paragraph [0006] of the subject application).

Clearly, applicants’ claims recite a self-expanding device to overcome the deficiencies of devices similar to the Huebsch device. Moreover, when considered in its entirety, the Huebsch reference simply fails to teach or suggest the requirements of applicant’s claims.

In view of the above amendments, applicant believes that Huebsch fails to anticipate claims 24 and 31 as well as any claim ultimately dependent therefrom.

Rejections under 35 U.S.C. §103(a)

Claims 30 and 37 are rejected under 35 U.S.C. §103(a) as being unpatentable over Huebsch et al. (5,853,422) in view of Goldstein et al. (U.S. Patent No. 6,143,037).

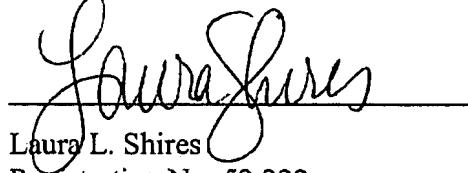
Applicant disagrees that the Office Action presents a proper *prima facie* case of obviousness. As noted above, Huebsch fails to teach or suggest the requirements of claims 24 or 31. The addition of Goldstein et al. does nothing to remedy this deficiency. As a result, applicant contends all pending claims are allowable and respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **TSNMNP00100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



Laura L. Shires
Registration No. 52,222

Customer No. 40518
Levine Bagade Han LLP
2483 East Bayshore Road, Suite 100
Palo Alto, CA 94303
Direct: (650) 242-4211
Fax: (650) 284-2180